AMENDMENT
U.S. Appln. No.10/766,748

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in this application:

Listing of Claims:

In the Claims:

1. (Previously Amended) A process for preparing an inhalable powder, wherein N+m substantially equal portions of an excipient having a larger average particle size [distribution] and N equal portions of an active substance having a smaller average particle size [distribution] are added in alternate layers into a suitable mixing vessel and after all the excipient and active substance have been added the 2N+m layers of the two components are mixed together using a suitable mixer, wherein a portion of the excipient having the larger particle size is added first, and wherein N is an integer >5 and m denotes 0 or 1.

2. (Cancelled)

3. (Original) A process according to claim 1, characterised in that the individual portions of excipient and active substance are added in layers through a suitable screening apparatus.

4. (Original) A process according to claim 1, characterised in that m denotes 1.

5. (Original) A process according to claim 1, characterised in that the inhalable powder obtained contains less than 5% of active substance.

6. (Original) A process according to claim 5, characterised in that the inhalable powder obtained contains less than 2% of active substance.

7. (Amended) A process according to claim 1, characterised in that the active substance has an average particle size of from 0.5 to 10 μm.

8. (Amended) A process according to claim 7, characterised in that the active substance has an average particle size of from 1 to 6 μm.

9. (Amended) A process according to claim 1, characterised in that the excipient has an average [mean] particle size of from 10 to 100 µm.

10. (Amended) A process according to claim 9, characterised in that the excipient has an average [mean] particle size of from 15 to 80 µm.

11. (Original) A process according to claim 1, wherein the excipient is a single excipient or a mixture of different excipients.

12. (Original) A process according to claim 1, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 µm and finer excipient with an average particle size of 1 to 9 µm, the proportion of finer excipient constituting 1 to 20% of the total amount of excipient.

13. (Original) A process according to claim 1, whercin the active substance is a single active substance or two or more different active substances.

14. (Original) A process according to claim 1, characterised in that the active substance consists of one or more compounds selected from among the betamimetics, anticholinergics, corticosteroids and dopamine agonists.

15. (Original) An inhalable powder obtained by the process according to claim 1.

16. (New) The process according to claim 1 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

17. (New) The process according to claim 16 wherein the active substance consists of an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

18. (New) The process according to claim 17 wherein the anticholinergic compound comprises tiotropium.

19. (New) The process according to claim 17 wherein the pharmaceutically acceptable salt of the anticholinergic compound comprises tiotropium bromide.

20. (New) The process according to claim 17 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound comprises tiotropium bromide monohydrate.

21. (New) The process according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate forms.

22. (New) The process according to claim 21 wherein the excipient consists of a monosaccharide or a disaccharide, or a combination thereof.

23. (New) The process according to claim 21 wherein the excipient consists of glucose or lactose or a combination thereof, each optionally in its hydrate form.

24. (New) The process according to claim 22 wherein the excipient consists of a disaccharide.

25. (New) The process according to claim 23 wherein the excipient consists of lactose or lactose monohydrate.

26. (New) The inhalable powder according to claim 15 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

27. (New) The inhalable powder according to claim 26 wherein the active substance consists of an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

28. (New) The inhalable powder according to claim 27 wherein the anticholinergic compound consists of tiotropium.

29. (New) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable salt of the anticholinergic compound consists of tiotropium bromide.

30. (New) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound consists of tiotropium bromide monohydrate.

31. (New) The inhalable powder according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate form.

32. (New) The inhalable powder according to claim 31 wherein the excipient consists of a monosaccharide or a disaccharide or a combination thereof.

33. (New) The inhalable powder according to claim 32 wherein the excipient consists of glucose or lactose or combinations thereof, each optionally in its hydrate form.

34. (New) The inhalable powder according to claim 32 wherein the excipient consists of a disaccharide.

35. (New) The inhalable powder according to claim 33 wherein the excipient consists of lactose or lactose monohydrate.

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1. (Previously Amended) A process for preparing an inhalable powder, wherein N+m substantially equal portions of an excipient having a larger average particle size and N equal portions of an active substance having a smaller average particle size are added in alternate layers into a suitable mixing vessel and after all the excipient and active substance have been added the 2N+m layers of the two components are mixed together using a suitable mixer, wherein a portion of the excipient having the larger particle size is added first, and wherein N is an integer >5 and m denotes 0 or 1.

2. (Previously Cancelled)

3. (Original) A process according to claim 1, characterised in that the individual portions of excipient and active substance are added in layers through a suitable screening apparatus.

4. (Original) A process according to claim 1, characterised in that m denotes 1.

5. (Original) A process according to claim 1, characterised in that the inhalable powder obtained contains less than 5% of active substance.

6. (Original) A process according to claim 5, characterised in that the inhalable powder obtained contains less than 2% of active substance.

7. (Currently amended) A process according to claim 1, characterised in that the active substance has an average particle size of from 0.5 to 10 μm.

8. (Currently amended) A process according to claim 7, characterised in that the active substance has an average particle size of from 1 to 6 μm.

9. (Currenlty amended) A process according to claim 1, characterised in that the excipient has an average ~~mean~~ particle size of from 10 to 100 µm.

10. (Currenlty amended) A process according to claim 9, characterised in that the excipient has an average ~~mean~~ particle size of from 15 to 80 µm.

11. (Original) A process according to claim 1, wherein the excipient is a single excipient or a mixture of different excipients.

12. (Original) A process according to claim 1, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 µm and finer excipient with an average particle size of 1 to 9 µm, the proportion of finer excipient constituting 1 to 20% of the total amount of excipient.

13. (Original) A process according to claim 1, wherein the active substance is a single active substance or two or more different active substances.

14. (Original) A process according to claim 1, characterised in that the active substance consists of one or more compounds selected from among the betamimetics, anticholinergics, corticosteroids and dopamine agonists.

15. (Original) An inhalable powder obtained by the process according to claim 1.

16. (Previously added) The process according to claim 1 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

17. (Currently amended) The process according to claim 16 wherein the active substance ~~comprises~~ consists of an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

18. (Previously added) The process according to claim 17 wherein the anticholinergic compound comprises tiotropium.

19. (Previously added) The process according to claim 17 wherein the pharmaceutically acceptable salt of the anticholinergic compound comprises tiotropium bromide.

20. (Previously added) The process according to claim 17 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound comprises tiotropium bromide monohydrate.

21. (Previously added) The process according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate forms.

22. (Currently amended) The process according to claim 21 wherein the excipient ~~comprises~~ consists of a monosaccharide or a disaccharide, or a combination thereof.

23. (Currently amended) The process according to claim 21 wherein the excipient ~~comprises~~ consists of glucose or lactose or a combination thereof, each optionally in its hydrate form.

24. (Currently amended) The process according to claim 22 wherein the excipient ~~comprises~~ consists of a disaccharide.

25. (Currently amended) The process according to claim 23 wherein the excipient ~~comprises~~ consists of lactose or lactose monohydrate.

26. (Previously added) The inhalable powder according to claim 15 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

27. (Currently amended) The inhalable powder according to claim 26 wherein the active substance ~~comprises~~ consists of an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

28. (Currently amended) The inhalable powder according to claim 27 wherein the anticholinergic compound ~~comprises~~ consists of tiotropium.

29. (Currently amended) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable salt of the anticholinergic compound ~~comprises~~ consists of tiotropium bromide.

30. (Currently amended) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound ~~comprises~~ consists of tiotropium bromide monohydrate.

31. (Previously added) The inhalable powder according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate form.

32. (Currently amended) The inhalable powder according to claim 31 wherein the excipient ~~comprises~~ consists of a monosaccharide or a disaccharide or a combination thereof.

33. (Currently amended) The inhalable powder according to claim 32 wherein the excipient ~~comprises~~ consists of glucose or lactose or combinations thereof, each optionally in its hydrate form.

34. (Currently amended) The inhalable powder according to claim 32 wherein the excipient ~~comprises~~ consists of a disaccharide.

35. (Currently amended) The inhalable powder according to claim 33 wherein the excipient ~~comprises~~ consists of lactose or lactose monohydrate.